K130197

510(K) Summary of Safety and Effectiveness

FEB 27 2013

Date Prepared: 25 January 2013

1. **Submitted By:**

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Tel: 201 847 5473; Fax: 201 847 5307

2. **Device Name:**

Trade Name:	BD PhaSeal Closed System Transfer Device – P55
Common Name:	Closed antineoplastic & hazardous drug reconstitution & transfer system
Classification Name:	Intravascular administration set
Classification:	Class II, 21 C.F.R. § 880.5440

3. **Predicate Device**

BD PhaSeal® Connector, Injector, Protector – K123213

4. **Device Description:**

The PhaSeal® System is a sterile single-used closed system drug transfer device. The closed transfer of liquid takes place through a double membrane utilizing self-sealing elastomeric membranes, tightly fitted together through a bayonet fitting on all PhaSeal components. A single lumen cannula perforates the double membranes for the transfer of liquid. When the cannula is retracted the membranes seal off the transfer of environmental contaminants into the system and/or escape of drug or vapor concentrations outside the system, thereby minimizing the individual and environmental exposure to drug vapor, aerosols and spills and also minimizing the risk of microbial contamination.

The PhaSeal Protector is one component of the PhaSeal system. It is a drug vial adapter that is fitted to the drug vial and is used as a docking station between the drug vial and the BD PhaSeal Injector. In addition the Protector equilibrates the pressure difference which occurs when fluid or air is added or removed from the drug vial. Liquid transfer takes place through tightly fitting elastomeric double membranes to minimize exposure to potentially hazardous drug aerosols and spills occurring during reconstitution, administration and disposal processes.

5. **Intended Use**

The PhaSeal system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor contractions outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal system also prevents microbial ingress.

XII. SMDA INFORMATION

A. 510(k) Summary

A 510(k) summary is provided in Attachment XII.1. This 510(k) Summary meets the requirements identified in 21 CFR §807.92.

B. Pre-Market Notification Truthful and Accurate Statement

As required per 807.87(k), an Accurate and Truthful Statement is provided in Attachment XII.2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 27, 2013

Mr. John Roberts
Regulatory Affairs Specialist
Becton, Dickinson and Company
1 Becton Drive MC237
FRANKLIN LAKES, NJ 07417

Re: K130197
Trade/Device Name: PhaSeal® - A Closed System Transfer Device – P55
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: ONB
Dated: January 25, 2013
Received: January 28, 2013

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130197

Device Name: PhaSeal® – A Closed System Transfer Device – P55

Indications for Use:

The PhaSeal system is an airtight and leakproof closed system drug transfer device (CSTD) that mechanically prohibits the transfer of environmental contaminants into the system and the escape of drug or vapor contractions outside the system, thereby minimizing individual and environmental exposure to drug vapor, aerosols and spills. The PhaSeal system also prevents microbial ingress.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

Gail G. Gantt

Digitally signed by Gail G. Gantt
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Gail G. Gantt, 0.9.2342.19200300.100.1.1=1300087388
Date: 2013.02.27 15:57:30 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130197